



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,221	11/17/2003	Jonathan J. Langberg	MITRAL.001C2	5022

30452 7590 12/07/2006

EDWARDS LIFESCIENCES CORPORATION  
LEGAL DEPARTMENT  
ONE EDWARDS WAY  
IRVINE, CA 92614

EXAMINER
----------

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/715,221	LANGBERG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) 25,35,39,41 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,26-34,36-38,40,42 and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the elements in claims 26,27,28,29 and 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Response to Amendment***

The amendment filed June 26, 2006 has been entered. Claims 1-23 and 47-49 have been canceled. Claims 24-46 are currently pending, of which claims 25, 35, 39, 41 and 43 have been withdrawn. The claims being considered for further examination on the merits are claims 24, 26-34, 36-38, 40, 42 and 44-46.

### ***Specification***

The disclosure is objected to because of the following informalities: paragraph [0001] must be updated to indicate that 09/968,272 is now U.S. Patent No. 6,709,456. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims are rejected under 35 U.S.C. 102(b) as being anticipated by Borghi [5482037].

Borghi discloses a medical apparatus comprising: an elongate body having a proximal end and a distal end, movable between a first configuration for transluminal delivery to at least a portion of the coronary sinus and a second configuration; a forming element attached to the elongate body at a point of attachment for manipulating the elongate body between the first transluminal configuration and the second configuration,

wherein the forming element is slidably contained within the elongate body between the attachment point and the proximal end; and an electrode, carried by the body.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-33, 37, 38, 40, 42 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borghi [5482037] in view of Swanson et al [5582609].

Borghi is not specific to the nature of the electrode. Swanson et al teaches various electrode configurations including annular band. To form the electrode of Borghi in the form of an annular band is but one known configuration in the art as taught by Swanson et al. It would have been obvious to one with ordinary skill in the art to look to Swanson et al for a teaching of electrode configurations known in the art and utilizing one such configuration depending upon in vivo constraints and criteria.

Claim 27, the electrode of Swanson extends away from the body as broadly worded.

Claims 28-30, the electrode of Swanson is coupled to various instruments including pacing source which is a form of rhythm management and diagnostic instruments.

Claims 31-34, see arcuate shape of the elongate body and the constant radius of curvature in the second configuration. The apparatus of Borghi is used to encircle the mitral valve and therefor would inherently possess the dimensions as claimed by applicant, since the two devices are employed in similar fashion.

With respect to claims 34 and 36, see securing means in paragraph 5. As broadly worded, the claim fails to distinguish over the same as disclosed by Borghi.

Claim 37, see coating in columns 12 and 16 of Swanson, et al.

Claim 38, see forming element of Borghi.

Claims 40 and 42, see anchor means 30 of Borghi.

Claims 44 and 45, see dimensions in Swanson et al. Moreover, the apparatus of Borghi is used to encircle the mitral valve and therefor would inherently possess the dimensions as claimed by applicant, since the two devices are employed in similar fashion.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 3738

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 24, 26-34, 36-38, 40, 42 and 44-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 6, 14, 17, 18, 20, 22, 24-26 and 30-32 of U.S. Patent No. 6,402,781 in view of Machek et al. The patent claims a medical apparatus for remodeling a mitral valve apparatus with all the elements of claim 24 but is silent to an electrode carried by the body. Machek et al. teach a lead assembly (10) comprising two expandable, electrode stents (40a, 40b) coupled to conductors (38) that reside in a lead (11), wherein the stents (40a, 40b) anchor the distal end (14) of the lead assembly (10) within the coronary sinus (22) and supply electrical impulses carried by the conductors (38) to the tissue for pacing and sensing. See Figure 2, 3, 4 and 7, column 3, lines 49-50, column 4, lines 35-39 and 53-62, and column 7, lines 2-6. The stent structure (23, 24, 25) in Figure 13 of Solem et al. and the stent structure (40a, 40b) in Figure 7 of Machek et al., are similar in that they are both cylindrical, expandable and appear to be of a mesh. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Machek et al. to include the lead assembly to the apparatus of Solem et al. by making the stents (23, 24, 25) into electrode stents by coupling them to conductors within a lead in a lead assembly in order for the stents to be used for sensing and pacing in addition to anchoring within the coronary sinus.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

With respect to the outstanding Double Patenting Rejection, contrary to applicant's assertion, the amendment to the claim fails to obviate the need for a terminal disclaimer.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

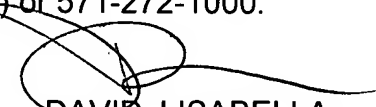
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
12/4/2006